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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,526	02/08/2006	Robert E Dudley	003168.1053	9100

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EXAMINER	
HUI SAN MING R	
ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
02/02/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,526	DUDLEY, ROBERT E	
	Examiner	Art Unit	
	San-ming Hui	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,8-16,19-23,25-27,30,32,34-38,41-45,47 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,8-16,19-23,25-27,30,32,34-38,41-45,47 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/20/2010 has been entered.

Claims 1, 4, 6, 8-16, 19-23, 25-27, 30, 32, 34-38, 41-45, 47, and 48 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 6, 8-16, 19-23, 25-27, 30, 32, 34-38, 41-45, 47-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7, 10-16, 18-23, 25-27, 30-33, 35-38, 40-45, and 47-48 of copending Application No. 10/867435 ('435). Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims in '435 significantly overlaps with that of the instant claims. For example, the active agents used, the penetrating enhancing agents, the gelling formulation are all similar, with different amount recited. Possessing the teachings of '435, one of ordinary skill in the art would have been motivated to adjust the weight amount of the herein claimed components in the method of treating erectile dysfunction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The amended claims recite the transitional phrase "consisting essentially of". Such transitional phrase, absent explicit disclosure of what the basic and novel characteristic of the instant invention in the specification, will be considered as "comprising" for the prior art searching purposes. (see below in examiner's response to the arguments)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 6, 8-16, 19-23, 25-27, 30, 32, 34-38, 41-45, 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,730,987 ('987), WO99/24041 ('041), and WO93/25168 ('168) in view of WO96/27372 ('372) and Hussain et al. (US 6,200,591, reference of record).

'987 teaches testosterone and other agents such as yohimbine or papaverin in a combination as useful in the a composition and method of treating impotent (erectile dysfunction) in human males(See col. 1, lines 17-65 and claims 6-8).

'041 teaches an enhancement of the penetration of transdermally or topically applied a pharmaceutical composition comprising an active agent, testosterone, and a penetration-enhancing system that comprises oleic acid (a C17 fatty acif), C1-C4 alcohol (e.g., ethanol, 2-propanol), and the gelling agents, CARBOPOL (See the abstract, page 3, lines 1-5, page 10, Example 1, and Fig. 2 for example).

'168 teaches testosterone composition comprising a transdermal delivery system comprising a C2 or C3 alcohol, a penetration-enhancersuch as glycerin and a gelling agent, as useful in methods of modulating and maintaining transdermal delivery of drug through the dermal layer at a relatively sustained rate over the duration of application to situs (See abstract, Example 3 at page 19-21, and claims 1-46 and 48 for example).

The primary references do not expressly teach the use of isopropyl myristate as the penetration enhancer. The primary references do not expressly teach the particular

composition comprising the specific recited components. The primary references do not expressly teach the use of PDE V inhibitor in the method of treating erectile dysfunction.

Hussain et al. teaches the method of intranasal administration of sildenafil citrate to treat erectile dysfunction (See abstract, Figure 1; col 2, lines 58-64; col. 10, Example 2 or 3), which may additionally include other pharmaceutical agents such as apopmorphine, papaverine, phentolamine and phenoxybenzamine (See col. 3, lines 23-28; col. 10, Example 4 or 5). Adminstration of one spray into eaxh nostril will deliver a total of 30mg of sildenafil HCl and apomorphine HCl (See col. 10, example 4). Hussain et al also teaches the combination therapies that use sildenafil and apomorphione or other pharmaceutical agents such as papaverine, phentolamine and phenoxybenzamine may be administered simultaneously or sequentially in separate formulations to reach a combined effect (See col. 3, lines 26-28; col. 8, lines 3-12).

'372 teaches a topical composition useful in treating male erectile dysfunction comprising isopropyl myristate or glycerine (See the abstract and claims 1and 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the specific penetration enhancer, isopropyl myristate, in the composition for treating erectile dysfunction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the particular composition which comprising the specific herein claimed components along with sildenafil in a method of treating erectile dysfunction.

One of ordinary skill in the art would have been motivated to employ the particular composition which comprising the specific herein claimed components along

with sildenafil in a method of treating erectile dysfunction. The composition of the cited prior art containing testosterone is well-known to be useful for treating erectile dysfunction. Penetration enhancer is known to be useful in enhancing the delivery of testosterone and thus, the efficacy and effectiveness of testosterone for treating ED. By incorporating penetrating-enhancing agent such as oleic acid, C1-C4 alcohol, and a penetration enhancer and gelling agent, the transdermal delivery rate of drug delivery can be adequately achieved and maintained according to '168.

One of ordinary skill in the art would have been motivated to employ the specific penetration enhancer, isopropyl myristate, in the composition for treating erectile dysfunction since incorporating another penetration enhancing agent such as isopropyl myristate would have been expected to be useful in further enhancing the drug delivery through the dermal layer. Furthermore, sildenafil and testosterone are well-known individually as useful in treating erectile dysfunction, concomitantly employ both agents in a method useful for the very same purpose is considered obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)).

Response to Arguments

Applicant's arguments filed 8/20/2010 averring the cited prior art's failure to teach or suggest the transdermal delivery of a composition consisting essentially of testosterone have been fully considered but they are not persuasive. The examiner notes that Tthe transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic of the claimed invention. For the purpose of searching for and

applying prior art under 35 USC 102 and 103, absent clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.") (See MPEP 2111.03). Furthermore, since the instant method comprising the administration other actives ingredients, the composition of '981 is not expected to change the basic and novel characteristics of the herein claimed method.

.No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
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